

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION  
CASE NO. 3:19-CV-643-RJC-DCK**

**SENSORRX, INC.,**

**Plaintiff**

**v.**

**ELI LILLY AND COMPANY,**

**Defendant.**

**PROTECTIVE ORDER**

**I. DEFINITIONS**

A. “Action” shall refer both to SensorRx, Inc. v. Eli Lilly and Company, 3:19-CV-643 and to Eli Lilly and Company v. SensorRx, Inc., No. 3:20-CV-351.

B. “Competitor” shall mean any company or individual that is or plans to be a manufacturer, developer, or seller of drugs other than Lilly or is or plans to be a developer, designer, owner, creator, or administrator of digital health applications other than SensorRx or Lilly or any person who, upon reasonable and good faith inquiry, could be determined to be an employee of any company or individual that plans to be a manufacturer, developer, or seller of drugs other than Lilly or is or plans to be a developer, designer, owner, creator, or administrator of digital health applications other than SensorRx or Lilly.

C. “Confidential Health Information” (“CHI”) shall mean any patient health information protected by any state or federal law, including, but not limited to, “Protected Health Information,” as defined below. CHI does not include any document or information in which the Producing Party has redacted the identifiers listed and does not have actual knowledge that information could be used alone or in combination with other information to identify an individual

who is the subject of the information. A Producing Party may, but is not required to, perform such redactions before producing documents that originally contained CHI so long as the redactions do not result in prejudice to another Party.

D. “Copies” shall mean any photocopies, reproductions, duplicates, extracts, summaries or descriptions of a document and/or Confidential Information.

E. “Customer” means any direct purchaser of products, including digital health applications, from Lilly, or any regular indirect purchaser of products from Lilly (such as a pharmacy generally purchasing through wholesale houses), and does not include physicians or individual patients. “Customer” shall also mean any healthcare system, healthcare provider, or other partner of SensorRx that distributes MigrnX to its patients. “Customer” shall also mean any healthcare system, healthcare provider, or other partner of Lilly that distributes any Lilly digital health applications to its patients.

F. “Documents” shall mean all “writings,” “recordings,” or “photographic” materials as described and defined in Rule 1001 of the Federal Rules of Evidence, including electronically stored information, whether produced or created by a Party or another person, and whether produced pursuant to Federal Rule of Civil Procedure 34, pursuant to a subpoena, by agreement or otherwise. This shall include, but not be restricted to, all interrogatory answers, responses to requests for production or for admission(s), deposition testimony, and deposition exhibits.

G. “Final conclusion of this litigation” shall mean the date fifteen (15) days following:

1. the Court’s entry of a stipulated dismissal,
2. the Court’s entry of a voluntary dismissal, or
3. the entry of a final, non-appealable order disposing of the case.

H. “Party” shall mean a Party to this Action, any employee of such Party, any retained experts of such Party, and any external counsel, including their paralegals and assistants, for such Party.

I. “Producing Party” shall mean any Party or its counsel or any other person or entity that produces document(s) in this Action.

J. “Protected Health Information” (“PHI”) has the same scope and definition as set forth in 45 C.F.R. § 160.103 and § 164.501. Without limiting the generality of the foregoing, PHI includes, but is not limited to, health information, including demographic information, relating to: the past, present, or future physical or mental health or condition of an individual; and the provision of health care to an individual, which identifies or reasonably could be expected to identify the individual. It also includes all notes, summaries, compilations, extracts, abstracts or oral communications that are based on or derived from PHI including payment for care provided to an individual, regardless of form or format. PHI also includes information that contains the following identifiers of a patient:

1. names;
2. all geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code;
3. all elements of dates (except year) directly related to an individual, including admission date, discharge date, age, and date of birth;
4. telephone numbers;
5. fax numbers;
6. electronic mail addresses;
7. social security numbers;

8. medical record numbers;
9. health plan beneficiary numbers;
10. account numbers;
11. certificate/license numbers;
12. vehicle identifiers and serial numbers, including license plate numbers;
13. device identifiers and serial numbers;
14. web universal resource locaters (“URLs”);
15. internet protocol (“IP”) address numbers;
16. biometric identifiers, including finger and voice prints;
17. full face photographic images and any compatible images;
18. any other unique identifying number; characteristic, or code; and
19. any other information that the Producing Party knows could be used alone or in combination with other information to identify an individual who is subject of the information.

K. “In the public domain” means able to be discussed and examined freely by the general public.

## **II. SCOPE OF PROTECTED INFORMATION**

In the course of discovery in this Action, the parties may be required to produce information that constitutes, in whole or in part, protected information such as trade secrets, non-public research and development, commercial or financial information, or other information that may cause harm to the producing party or a non-party. The parties anticipate production of the following categories of protected information:

A. Confidential Information: Confidential Information shall include all documents or portions thereof that the Designating Party believes is subject to protection under this Protective Order under Federal Rule of Evidence 502(d), Federal Rule of Civil Procedure 26(c)(1), or other state or federal law. “Confidential Information” includes but is not limited to “Confidential Health Information.”

B. Highly Confidential – Attorneys’ Eyes Only Information: Highly Confidential – Attorneys’ Eyes Only Information shall include any Confidential Information that the Designating Party reasonably believes contains highly sensitive confidential information, the disclosure of which could result in significant competitive or commercial disadvantage to the Designating Party.

### **III. DESIGNATION OF PROTECTED INFORMATION**

A. Scope: This Order governs the production and handling of any protected information in this Action. Any party or non-party who produces protected information in this Action may designate it as “Confidential” or “Attorneys’ Eyes Only” consistent with the terms of this Order. “Designating Party” means the party or non-party who so designates the protected information; “Receiving Party” means the party or non-party to whom such information was produced or disclosed.

The failure to designate a document or any portion thereof as confidential does not alter or waive the protected and confidential nature of the document or portion thereof and does not remove it from the scope of this Order. The Party discovering such failure to designate a document or portion thereof as confidential shall, within fifteen (15) days of such discovery notify counsel for the Receiving Party in writing that the document or a specified portion thereof is to be designated as confidential under the terms of this Order.

To the extent that any Party has heretofore designated certain documents as confidential, it will not be required to re-designate the same with the full legend set out in Paragraph IV.D., below.

Regardless of any designations made hereunder, the Designating Party is not otherwise restricted from use or disclosure of its protected information outside of this Action. In addition, any party may move to modify or seek other relief from any of the terms of this Order if it has first tried in writing and in good faith to resolve its needs or disputes with the other party(ies) pursuant to the terms of this Order and S.D. Ind. L.R. 37-1.

This Protective Order does not offer protection for the following information: (a) any information that is in the public domain at the time of disclosure to a Receiving Party or becomes part of the public domain after its disclosure to a Receiving Party as a result of publication not involving a violation of this Order, including becoming part of the public record through trial or otherwise; and (b) any information known to the Receiving Party prior to the disclosure or obtained by the Receiving Party after the disclosure from a source who obtained the information lawfully and under no obligation of confidentiality to the Designating Party. However, all documents produced for this Action designated as “CONFIDENTIAL” or “ATTORNEYS’ EYES ONLY” per the below Section IV.D. shall be treated as so designated until resolution of any challenge pursuant to below Section V.

B. Application to Non-Parties: Before a non-party is given copies of designated information as permitted hereunder, the non-party must first sign the acknowledgment to be bound to these terms that is attached hereto as Exhibit A; if it fails to do so, the parties to this Action must resolve any such dispute before making disclosure of designated information as permitted hereunder to the non-party. If a non-party wishes to make designations hereunder, it must first sign the acknowledgment to be bound to these terms that is attached hereto as Exhibit A.

C. Timing and Provisional Protection: Designations may be made at any time. To avoid potential waiver of protection hereunder, the Designating Party should designate information at the time of production or disclosure, including on the record during the taking of any testimony. Deposition testimony will be deemed provisionally protected for a period of 30 days after the transcript is released to the parties by the court reporter, although the parties may agree at any time to different timelines of provisional protection of information as Confidential or Attorneys' Eyes Only as part of one or more specific depositions. To retain any designations beyond the provisional period, a Designating Party must designate all testimony, each deposition transcript, recording, or portions thereof before the provisional period has expired. Such designations must be made in writing so that all counsel and court reporters may append the designation to all copies of the transcripts.

D. Manner of Designation: Information may be designated hereunder in any reasonable manner or method that notifies the Receiving Party of the designation level and identifies with specificity the information to which the designation applies. If made verbally, the Designating Party must promptly confirm in writing the designation. Whenever possible, the Designating Party should stamp, affix, or embed a legend of "CONFIDENTIAL" or "ATTORNEYS' EYES ONLY" on each designated page of the document or electronic image.

E. Confidential Documents From Other Sources: If a Party receives the other Party's documents that are not publicly available from any source other than the other Party that, upon reasonable and good faith inquiry, appear to be documents authored or created by the other Party, the Party receiving the other Party's documents will treat such documents as confidential under the terms of this Protective Order. In the event the receiving Party produces to the other Party pursuant to Rule 34 of the Federal Rules of Civil Procedure any document(s) falling within this

paragraph, the other Party shall have thirty (30) days after the date of discovery of the produced confidential information to designate said documents as confidential pursuant to paragraph IV. If the Producing Party wishes to challenge the confidentiality of such a document, the Producing Party shall promptly notify the other Party in writing and append a copy of the document at issue.

F. Waiver of any Provision to any Document: Any Party may expressly waive in writing the applicability of any provision of this Order to any document or portion thereof that the Party produces. Such waiver shall apply only to the document or portion thereof to which the applicability of the specified provision of this Order is expressly waived.

#### **IV. CHALLENGES TO DESIGNATED INFORMATION**

In the event that a Receiving Party disagrees at any time with any designation(s) made by the Designating Party, the Receiving Party must first try to resolve such challenge in good faith on an informal basis with the Designating Party pursuant to S.D. Ind. L.R. 37-1. The Receiving Party must provide written notice of the challenge and the grounds therefor to the Designating Party, who must respond in writing to the challenge within 15 days. At all times, the Designating Party carries the burden of establishing the propriety of the designation and protection level. Unless and until the challenge is resolved by the parties or ruled upon by the Court, the designated information will remain protected under this Order. The failure of any Receiving Party to challenge a designation does not constitute a concession that the designation is proper or an admission that the designated information is otherwise competent, relevant, or material.

#### **V. LIMITED ACCESS/USE OF PROTECTED INFORMATION**

A. Restricted Use: Information that is produced or exchanged in the course of this Action and designated under this Order may be used solely for the preparation, trial, and any appeal of this Action as well as related settlement negotiations, and for no other purpose, without the



written consent of the Designating Party. No designated information may be disclosed to any person except in accordance with the terms of this Order. All persons in possession of designated information agree to exercise reasonable care with regard to the custody, use, or storage of such information to ensure that its confidentiality is maintained. This obligation includes, but is not limited to, the Receiving Party providing to the Designating Party prompt notice of the receipt of any subpoena or other process that seeks production or disclosure of any designated information and consulting with the Designating Party before responding to the subpoena.

Any Party or person to whom Confidential Information (including Highly Confidential – Attorneys’ Eyes Only Information) has been furnished who receives from any non-party (including natural persons, corporations, partnerships, firms, governmental agencies, departments or bodies, boards or associations) a subpoena or other process that seeks production or disclosure of such Confidential Information (including Highly Confidential – Attorneys’ Eyes Only Information) shall promptly, and in any case by the close of the next business day, give telephonic and written notice by overnight mail, e-mail, or facsimile to counsel for the Designating Party. Both the telephonic and written notice shall identify the documents sought and the return date of the subpoena or other process, and the written notice shall also include a copy of the subpoena or other process. The Party or person receiving the subpoena shall also inform the person seeking the Confidential Information (including Highly Confidential – Attorneys’ Eyes Only Information) that such information is subject to this Order. No production or other disclosure of such information pursuant to the subpoena or other process shall occur before ten (10) days following the date on which notice is given, or the return date of the subpoena, whichever is earlier.

Any Confidential Health Information shall be deemed “Confidential” and, as such, subject to the terms of this Protective Order. All persons who receive and store Confidential Health

Information will develop, implement, maintain, and use appropriate administrative, technical, and physical safeguards to preserve the privacy, integrity, and confidentiality of any Confidential Health Information and to prevent the unpermitted use or disclosure of any Confidential Health Information they receive from any person in connection with this proceeding. Confidential Health Information will be securely returned or destroyed pursuant to the provisions of Paragraph X.A., below. Any use or disclosure of Confidential or Attorneys' Eyes Only information in violation of the terms of this Order may subject the disclosing person or party to sanctions.

B. Counsel of record for the Receiving Party shall use reasonable efforts to limit the disclosure of Confidential Information (including Highly Confidential – Attorneys' Eyes Only Information), including any copies thereof, to the minimum number of persons eligible to receive Confidential Information (including Highly Confidential – Attorneys' Eyes Only Information) per Paragraphs VI.C and D of this Order who are necessary to conduct this litigation. The documents, the information contained therein, and all other information produced or disclosed during this matter shall not be used in any other proceeding or Action other than for this Action. All copies of Confidential Information (including Highly Confidential – Attorneys' Eyes Only Information) shall immediately be affixed with the confidentiality legend pursuant to the provisions of Paragraph IV.D, above.

C. Access to "Confidential" Information: The parties and all persons subject to this Order agree that information designated as "CONFIDENTIAL" may only be accessed or reviewed by the following:

1. The Court, its personnel, and court reporters;

2. Counsel of record for any party in this Action and any paralegal or legal assistant of said counsel who assists counsel of record in this Action and are informed of the duties hereunder;
3. The parties, including their agents and employees who are assisting or have reason to know of this Action, so long as each such agent or employee has signed the acknowledgment to be bound to these terms that is attached hereto as Exhibit A;
4. Subject to the provisions of Paragraph VI.E., below, any of the following:
  - a. Any person who is an author, copyee or addressee of Confidential Information; however, the person seeking access to Confidential Information under this subsection is expressly limited to Confidential Information that the person has authored or on which he/she is listed as a copyee or addressee and only to the extent reasonably necessary for the preparation and trial of this Action;
  - b. Experts or consultants employed by the parties or their counsel for purposes of this Action, so long as each such expert or consultant has signed the acknowledgment to be bound to these terms that is attached hereto as Exhibit A and is subject to the disclosure requirements in Paragraph VI.E;
  - c. Any employee or third party contractor of counsel involved in organizing, filing, coding, converting, storing or retrieving data or in designing programs for handling documents or data connected with

these Actions, including the performance of such duties in relation to a computerized litigation support system;

- d. Any employee or third party contractor of counsel involved in trial preparation; and
- e. Other witnesses or persons to whom the Designating Party agrees in advance of disclosure or by court order.

D. Access to “Attorneys’ Eyes Only” Designations: The parties and all persons subject to this Order agree that information designated as “ATTORNEYS’ EYES ONLY” may only be accessed or reviewed by the following:

- 1. The Court, its personnel, and court reporters;
- 2. Counsel of record for any party in this Action and any paralegal or legal assistant of said counsel who assists counsel of record in this Action and are informed of the duties hereunder;
- 3. A party’s in-house lawyers involved in managing the litigation and who have signed the acknowledgment to be bound to these terms that is attached hereto as Exhibit A, as well as any paralegal or legal assistant who assists the in-house lawyers and are informed of the duties hereunder;
- 4. Subject to the provisions of Paragraph VI.E., below, any of the following:
  - a. Any person who is an author, copyee or addressee of Attorneys’ Eyes Only Information; however, the person seeking access to Attorneys’ Eyes Only Information under this subsection is expressly limited to Attorneys’ Eyes Only Information that the person has authored or on

which he/she is listed as a copyee or addressee and only to the extent reasonably necessary for the preparation and trial of this Action;

- b. Experts or consultants employed by the parties or their counsel for purposes of this Action, so long as each such expert or consultant has signed the acknowledgment to be bound to these terms that is attached hereto as Exhibit A and is subject to the disclosure requirements in Paragraph VI.E, below;
- c. Any employee or third party contractor of counsel involved in organizing, filing, coding, converting, storing or retrieving data or in designing programs for handling documents or data connected with these Actions, including the performance of such duties in relation to a computerized litigation support system;
- d. Any employee or third party contractor of counsel involved in trial preparation; and
- e. Other witnesses or persons to whom the Designating Party agrees in advance of disclosure or by court order.

E. Agreement to Be Bound by Protective Order: Before disclosing Confidential or Attorneys' Eyes Only information to any person listed in Paragraph VI.C.4. or Paragraph VI.D.4, above, the Receiving Party shall ensure that the individual to whom disclosure is to be made has been provided a copy of this Order and signed the acknowledgment to be bound to these terms that is attached hereto as Exhibit A. In addition, for any person listed in Paragraph VI.C.4.b or Paragraph VI.D.4.b (consultants and experts), the Receiving Party must identify such expert or consultant in a writing sent by email to counsel for the Producing Party. This identification shall

include the full name and professional address and/or affiliation of the proposed expert or consultant, an up-to-date curriculum vitae, any prior or current employments or consultancies for any party or other company in the pharmaceutical or digital health industry within the last 5 years (except those engagements that are protected from disclosure pursuant to Fed. R. Civ. P. 26), including a list of the cases in which the expert or consultant has testified at deposition, at a hearing, or at trial within the last four years. The Receiving Party shall have 5 business days from receipt of such notice to object in writing to disclosure of such information to any of the experts or consultants so identified. Any party that fails to object in writing within 5 business days of receiving such notice shall be deemed to have waived such objection and the parties shall be deemed to have agreed upon disclosure to the expert, unless otherwise ordered by the Court for good cause shown. The parties shall attempt to resolve any objections informally. If the objections cannot be resolved, the party opposing disclosure of the Confidential Information (including Highly Confidential – Attorneys’ Eyes Only Information) to the expert or consultant shall have 10 business days to raise the issue with the Court in accordance with the Court’s procedures for resolution of discovery disputes, or else the objection shall be waived and the parties shall be deemed to have agreed upon disclosure to the expert or consultant, unless otherwise ordered by the Court for good cause shown. If the issue is raised with the Court, the party opposing disclosure shall bear the burden of proof with respect to the propriety of its objection as to the disclosure of Confidential Information (including Highly Confidential – Attorneys’ Eyes Only Information) to the expert or consultant. No Confidential Information (including Highly Confidential – Attorneys’ Eyes Only Information) may be disclosed to any proposed expert or consultant until the parties are deemed to have agreed upon disclosure to the expert or consultant.

F. Non-Waiver Effect of Designations: Neither the taking of, nor the failure to take, any action to enforce the provisions of this Order, nor the failure to object to any designation, will constitute a waiver of any party's claim or defense in this Action or any other action or proceeding, including but not limited to a claim or defense that any designated information is or is not confidential, is or is not entitled to particular protection, or embodies or does not embody information protectable by law.

G. Deponent Examination: A deponent may be shown and examined about Confidential Information during a deposition subject to the terms of Paragraphs VI.C., D., and E., above. Deponents shall not retain or copy portions of the transcript of their depositions that contain Confidential Information not provided by them or their counsel. While a deponent is being examined about any information designated Confidential or Attorneys' Eyes Only, persons to whom disclosure is not authorized under this Order shall not be present.

H. In-Court Use of Designated Information: If information designated pursuant to this Order will or may be offered in evidence at a hearing or trial, then the offering party must give five (5) days' advance notice in writing to the party or non-party that designated prior to offering the information so that any use or disclosure may be addressed in accordance with the Court's case-management or other pre-trial order, or by a motion *in limine*.

Nothing in this Order shall be construed as a waiver by a party of any objections that may be raised as to the admissibility at trial of any evidentiary materials.

I. Rendering Advice to Clients in this Lawsuit: Nothing in this Order shall prevent or otherwise restrict counsel from rendering advice to their clients in this lawsuit and, in the course thereof, relying generally on examination of Confidential Information, provided that, in rendering such advice and otherwise communicating with a client, counsel shall not make specific disclosure

of any Confidential Information except pursuant to the provisions of this Order. Counsel shall at all times keep secure all notes, abstractions, or other work product derived from or containing Confidential Information and shall be obligated to maintain the confidentiality of such work product, even after the documents designated as confidential have been returned or destroyed pursuant to Paragraph X.

## **VI. REDACTIONS**

A. The Producing Party may redact the following Confidential Information or information subject to attorney-client privilege, work product doctrine, or other legal protection of information from discovery in this lawsuit from documents that it produces:

1. individually identifiable patient information such as names, addresses, social security numbers, tax identification numbers, e-mail addresses, telephone numbers, and any other Confidential Health Information defined in Paragraph II.C;
2. names, addresses, social security numbers, tax identification numbers, e-mail addresses, telephone numbers, and any other personal identifying information (not to include race, age, or gender) of individuals enrolled as subjects in clinical studies or identified in adverse event reports;
3. names, addresses, social security numbers, tax identification numbers, e-mail addresses, telephone numbers, and any other personal identifying information of any person involved in the reporting of an adverse event;
4. street addresses, social security numbers, tax identification numbers, dates of birth, home telephone numbers, cellular telephone numbers, and other personal information of current or former employees;



5. names, addresses, social security numbers, tax identification numbers, e-mail addresses, telephone numbers, and any other personal identifying information of any clinical investigator involved in the reporting of an adverse event;
  6. information necessary to comply with privacy rights that are guaranteed by the United States Constitution, the Code of Federal Regulations, the Health Insurance Portability and Accountability Act of 1996, and other applicable state constitutions, laws, and regulations. *See, e.g.*, 21 C.F.R. §§ 20.111, 20.63, and 314.80; 45 C.F.R. §§ 160 and 164;
  7. non-relevant trade secret and confidential commercial information, including:
    - i. any information related to products not relevant for this matter;
    - ii. any information related to marketing or sales of the Producing Parties products outside the United States;
    - iii. non relevant information protected by non-party confidentiality agreement(s); and
  8. materials that contain information protected from disclosure by attorney-client privilege, work product doctrine, or other legal privilege or doctrine protecting information from disclosure.
- B. Redaction of material pursuant to Paragraph VII.A. is subject to the following:
1. The following terms will be used to signify the reasons for any redactions on the basis of privilege: AC Privilege, WP Privilege, or AC/WP Privilege. The following terms will be used to signify the reasons for redaction of

non-relevant confidential information: Confidential Personal Information for employees (“CEI”), Confidential Patient Information (“CPI”), and Confidential Non-Relevant Information (“CNR”). The Party that has redacted information shall, upon written or oral request, identify the nature of the information redacted in a specific document with sufficient detail to allow the requesting Party to determine whether a challenge to the redacted information may be appropriate.

2. If the requesting Party has a good faith basis for challenging the redaction, that Party shall promptly inform counsel for the redacting Party in writing of said challenge.
3. If, after conferring, the Parties cannot resolve the dispute despite good faith efforts to do so, the Party challenging the redaction may move for a ruling on the issue of whether certain information is entitled to redaction. If the Court finds that said information should not remain redacted, the redacting Party shall provide an unredacted version of the document within fifteen (15) days of the Court’s decision or, if the redacting Party challenges such a decision, within fifteen (15) days of the conclusion of any and all proceedings or interlocutory appeals challenging the decision, or within any time specified by the Court or local rules if they dictate a shorter period for production.
4. The following terms will be used to signify the redactions of Confidential Information or redactions of privileged information: Redacted, AC Privilege, WP Privilege, and AC/WP Privilege.

## **VII. PRIVILEGE LOGS**

A. Within sixty (60) days after each production, absent agreement of the Parties, the Producing Party shall provide the Receiving Party with a log of the documents entirely withheld from production for a claim of attorney-client privilege, work product protection, or other applicable privilege or immunity.

1. A Party's privilege log only needs to provide objective metadata (to the extent it is reasonably available and does not reflect privileged or protected information) and an indication of the privilege or protection being asserted. The log will be produced in Excel or CSV format, and will be populated with the following extracted metadata fields, to the extent providing this information will not destroy privilege: Custodian, From, To, CC, BCC, Subject, File Name, File Extension, Date Sent, Date Created, Date Last Modified. In-house attorney names shall be designated with an asterisk; outside counsel names will be designated with a double asterisk. An e-mail thread may be logged as a single entry to the extent the entire thread is claimed to be protected by the applicable privilege or protection.
2. No Party is required to list on a privilege log any communications regarding the claims and defenses in these proceedings exclusively between a Party and its in-house counsel, outside counsel, an agent of outside counsel other than the Party, any non-testifying experts, and, with respect to information protected by Fed. R. Civ. P. 26(b)(4), testifying experts.

3. No Party is required to list on a privilege log any privileged materials or work product relating to the claims and defenses in these proceedings created by its in-house counsel, outside counsel, an agent of outside counsel other than the Party, any non-testifying experts, and, with respect to information protected by Fed. R. Civ. P. 26(b)(4), testifying experts.
4. If a Producing Party redacts portions of the discoverable information for privilege, the Producing Party does not need to provide a log entry where the face of the redacted discoverable information provides the information that otherwise would appear on a log. Redacted documents need not be logged as long as: (a) for e-mails, the bibliographic information (i.e., To, From, CC, BCC, Date/Time) is not redacted, and the reason for the redaction is noted on the face of the document in the redaction box; and (b) for non-e-mail documents, the redaction is noted on the face of the document in the redaction box.
5. If a Party receiving a privilege log has a good faith basis for challenging a Producing Party's privilege determination, the Receiving Party shall meet and confer with the Producing party pursuant to S.D. Ind. L.R. 37-1.
6. If, after conferring, the Parties cannot resolve the dispute despite good faith efforts to do so, the Party challenging a privilege determination may move for a ruling on the issue of privilege. The Producing Party bears the burden of establishing that the withheld material is privileged. If the Court finds that said information is privileged, said information shall remain withheld or redacted and may not be used as evidence by either Party at trial or at a

hearing or be relied upon by either Party's experts. If the Court finds that said information is not privileged, the Producing Party shall provide an unredacted version of the document within ten (10) days of the Court's decision or, if the Producing Party challenges such a decision, within ten (10) days of the conclusion of any and all proceedings or interlocutory appeals challenging the decision, or within any time specified by the Court or local rules if they dictate a shorter period for production.

### **VIII. CLAW-BACK REQUESTS**

A. Failure to Make Designation: If, at any time, a party or non-party discovers that it produced or disclosed protected information without designation, it may promptly notify the Receiving Party and identify with particularity the information to be designated and the level of designation (the claw-back notification). The Receiving Party may then request substitute production of the newly-designated information. Within 30 days of receiving the claw-back notification, (1) the Receiving Party must certify to the Designating Party it has appropriately marked or, if substitute production has been requested, destroyed all unmarked copies that it received, made, and/or distributed; and (2) if it was practicably unable to mark or destroy any information because disclosures occurred while the Receiving Party was under no duty of confidentiality under the terms of this Order regarding that information, the Receiving Party must reasonably provide as much information as practicable to aid the Designating Party in protecting the information, consistently with the Receiving Party's attorney-client, work-product, and/or trial-preparation privileges.

B. Dispute Regarding Level of Designation: If the Party in possession believes that the documents are not subject to the requested level of designation, the Party in possession shall

contact the opposing counsel for a meet and confer. To the extent the parties are unable to resolve the dispute, the Party in possession may contact the Court and opposing counsel to request an in camera review of the materials in question. Any Party requesting an in camera review shall comply with S.D. Ind. L.R. 37-1 before making any such request. The party making the designation bears the burden of demonstrating that the designated material was properly designated. If the Court determines that the produced documents are entitled to the requested level of designation, the Party in possession shall, within fifteen (15) days of the Court's decision, comply with the provisions of Paragraph VII.A., above.

C. Production of Privileged Information: If a Producing Party discloses information subject to a claim of attorney-client privilege or work product protection or some other legal privilege or doctrine protecting information from disclosure, the disclosure of that information ("Protected Information") shall not constitute or be deemed a waiver or forfeiture of any claim of privilege or work product protection that the Designating Party would otherwise be entitled to assert with respect to the produced information and its subject matter. This provision is, and shall be construed as, an Order under Federal Rule of Evidence 502(d). Accordingly, as explicitly set forth in Rule 502(d), a Party's production of Protected Information, whether inadvertent or otherwise, is not a waiver of any privilege or protection "in any other federal or state proceeding." With respect to such produced documents, the following procedures shall apply, and the Parties agree that such procedures constitute reasonable and prompt steps to prevent disclosure and to rectify the error of disclosure, pursuant to the Federal Rules of Civil Procedure:

1. The Party discovering the production will contact the opposing Party to apprise that Party of such production within 14 business days of such discovery. Upon receipt of notice of produced documents containing

Protected Information, no use shall be made of the identified produced documents during depositions or at trial, nor shall they be disclosed to anyone who did not previously have access to them.

2. If no dispute exists as to the protected nature of the produced documents, any Party in possession of the documents at issue shall return the materials to the Producing Party, and destroy any notes or other work product reflecting the contents of such materials. Alternatively, upon request of the Producing Party, the Party discovering the production shall destroy such materials and provide a written assurance to the Producing Party confirming destruction within fifteen (15) days. In either event, all material shall be deleted from any litigation-support or other database, and all copies of the protected documents provided by the Receiving Party to other persons or entities shall be returned or destroyed. If destroyed, the Party that received the materials shall provide a written assurance to the Party that produced the materials confirming destruction within fifteen (15) days. In the event that only portions of the produced documents contain privileged subject matter, the Producing Party shall substitute redacted versions of the documents within ten (10) days of the certification of destruction of the produced documents.
3. If the Party in possession believes that the documents are not subject to the protections of work product immunity, attorney-client privilege or other legal privilege protecting information from discovery, the Party in possession shall contact the Court and opposing counsel for an in camera

review of the materials in question. Any Party requesting an in camera inspection shall confer with opposing counsel and also comply with S.D. Ind. L.R. 37-1 before seeking Court intervention to resolve any related dispute before making any such request. The party that is asserting the privilege or protection bears the burden of demonstrating that the privilege or protection is applicable. If the Court determines that the produced documents are entitled to work product immunity, attorney-client privilege or other legal privilege protecting information from discovery, the Party in possession shall, within fifteen (15) days of the Court's decision, comply with the provisions of Paragraph IX.C.2., above.

4. The Parties agree that employing electronic keyword searching to identify and prevent disclosure of privileged material constitutes "reasonable steps to prevent disclosure" under Federal Rule of Evidence 502(b)(2).
5. Pursuant to Federal Rule of Evidence 502(d) and (e), the production of any discovery material by any Party shall be without prejudice to any subsequent claim by the Producing Party that such discovery material is privileged or attorney work product, and shall not be deemed a waiver of any such privilege or protection in either the litigation pending before the Court, or any other federal or state proceeding.

#### **IX. DURATION/CONTINUED RESTRICTIONS**

A. Handling of Designated Information Upon Conclusion of Action: Upon conclusion of this Action, including all appeals, the Designating Party(ies) is/are responsible for ensuring that any party or person to whom the party shared or disclosed designated information, including



Protected Health Information, in this Action returns or destroys all of its copies, regardless of the medium in which it was stored.

The Receiving Party shall make a reasonable effort to retrieve any Confidential Information from any non-party to whom such information has been given, and shall notify the Designating Party in writing of any failure to retrieve any such documents. This notice shall (1) specifically identify the Confidential Information not returned, (2) identify the person from whom the Confidential Information could not be retrieved, and (3) state the efforts made to retrieve such Confidential Information and the reasons these efforts were unsuccessful.

No witness or party may retain designated information that it received from any other party or non-party under this Order. Unless otherwise ordered by the Court, only counsel of record are the authorized agents who may retain (1) copies of pleadings or other papers that have been filed with the Court that contain Confidential Information, including exhibits thereto; (2) work product containing Confidential Information; (3) official transcripts and exhibits thereto for their respective legal files; and (4) documents produced in discovery by any party or non-party. This provision does not apply to the Court or Court staff. All Parties shall make certification of compliance with this paragraph and shall deliver the same to the Producing Party not more than 45 days after the final conclusion of this litigation. This provision is, and shall be construed as, satisfying the requirements for a Qualified Protective Order under 45 CFR § 164.512(e)(1)(v).

Nothing in this Order shall prevent any Party or other person from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper. The Parties shall be given notice and an opportunity to be heard before the Court on any matter that in any way modifies this Order or may result in a decision affecting the substance or effect of this Order.

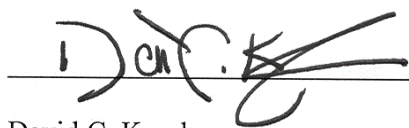
B. Continued Restrictions Under this Order: The restrictions on disclosure and use of Confidential Information survive the conclusion of this Action. The provisions of this Order shall not terminate at the final conclusion of this litigation. This Order shall remain in full force and effect in perpetuity unless modified, superseded, or terminated by written consent of the Parties or by order of the Court. Each person subject to this Order shall continue to be subject to the jurisdiction of the United States District Court for this Action for the purpose of enforcement of the terms of this Order for as long as the Order or any successor Order remains in effect. The Court(s) shall not be divested of the power to enforce the terms of this Order as to any person subject to the Order by the final conclusion of this litigation or by the filing of a notice of appeal or other pleading that arguably has the effect of divesting this Court of jurisdiction of this matter generally.


#### **XI. REQUESTS TO SEAL**

This protective order does not authorize a party to file or maintain a document under seal. To the extent a Party seeks to file any Confidential Information in the public record in this Action, that filing Party shall give at least five (5) days' notice to the other Party to allow the Party time to review the Confidential Information and, if appropriate, file a motion to seal in accordance with **Local Rule 6.1**. The Parties shall act in good faith to not include or attach Confidential Information to filings in the public record unless the Confidential Information has direct relevance to the submission to the Court.

**SO ORDERED.**

Signed: July 28, 2020

  
\_\_\_\_\_  
David C. Keesler  
United States Magistrate Judge



**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION  
CASE NO. 3:19-CV-643-RJC-DCK**

**SENSORRX, INC.,**

**Plaintiff**

**v.**

**ELI LILLY AND COMPANY,**

**Defendant.**

**AGREEMENT TO BE BOUND BY PROTECTIVE ORDER**

The undersigned acknowledges having been provided with and having read the Protective Order. The undersigned further agrees he/she (i) is bound under the Protective Order, (ii) will comply with all of its provisions, and (iii) is subject to the jurisdiction of the Court for all purposes arising under the Protective Order, including enforcement of its terms.

[INSERT DATE & SIGNATURE BLOCK WITH WITNESS ATTEST]